REMARKS

In response to a restriction requirement, claims 16-21 have been withdrawn.

In the Office Action, claims 1-3 and 7-11 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,628,774 to Helland et al.

In response to a restriction requirement, claims 16-21 have been withdrawn.

In the Office Action, claims 4-6 and 12-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,628,774 to Helland et al. in view of U.S. Patent No. 6,078,839 to Carson.

In response thereto, claim 1 has been amended and new claims 22-25 have been added. Accordingly, claims 1-15 and 22-25 are now pending.

Independent Claim 1

Claim 1 recites a lead body comprising an insulating housing, a flexible membrane surrounding the insulating housing, and a lubricious medium disposed between the inner surface of the membrane and an outer surface of the housing. The flexibility of the membrane and the properties of the lubricious medium enable the membrane to slide over the insulating housing and deform as the insulating housing moves relatives to a patient's body tissue. The relative motion between the membrane and the insulating house reduces abrasive wear of the lead body.

The Helland et al. reference discloses an implantable lead having a composite insulating structure formed from two different insulating materials, one overlying the other, which results in a lead having superior overall characteristics. In one embodiment, the implantable lead has a relatively thick silicone insulation tubing and a relatively thin polyurethane insulation tubing. The polyurethane insulation tubing may be disposed over the silicone insulation tubing with isopropyl alcohol to reduce the friction of the silicone to polyurethane and then quickly sliding the polyurethane insulation tubing over the silicone insulation tubing.

In accordance with the Helland et al. reference (see column 5, lines 62 through column 6, line 4), silicone is more biostable and flexible than polyurethane. As a result, the silicone insulation tubing provides biolstability, electrical insulation for the leads, and flexibility. Hence, the leads capitalize on these desired characteristics of the silicone insulation. At the same time, the rather inferior biodegration characteristics of the polyurethane insulation are minimized or negated because the silicone insulation tubing protects the polyurethane insulation tubing from the biodegration effects of failure such as metal ion induced oxidation. In addition, the polyurethane provides the following advantages over silicone: greater blood compatibility characteristics, lower coefficient of friction in blood, and greater durability in terms of tensile, toughness, and wear characteristics. As a result, the leads will capitalize on the characteristics of polyurethane for the surface of the lead and the characteristics of silicone for the inner body of the lead.

The Helland et al. reference does not disclose or suggest that the flexibility of the membrane and the properties of the lubricious medium enable the flexible membrane to slide over the insulating housing and deform as the lead insulating housing moves relative to a patient's body tissue. Furthermore, the Helland et al. reference does not disclose or suggest that relative motion between the flexible membrane and the insulating housing reduces abrasive wear of the lead body. As discussed previously, it appears that the Helland et al. reference is directed to providing a lead having the desired characteristics of both polyurethane and silicone by disposing a polyurethane insulation tubing over a silicone insulation tubing. With such a configuration, the lead benefits from the desired surface characteristics of polyurethane and the desired inner body characteristics of silicone. No where does the Helland et al. reference disclose or suggest that abrasion resistance can be improved by enabling the polyurethane insulation tubing to deform as the lead silicone insulation tubing moves relative to a patient's body tissue, nor does the Helland et al. reference disclose or suggest relative motion between the polyurethane insulation tubing and the silicone insulation tubing. It appears that the friction between the outer surface of the silicone insulating tubing and the inner surface of the polyurethane insulation tubing may prevent relative motion

between the respective elements. As stated previously, the Helland et al. reference teaches that the outer surface of the silicone insulation tubing is coated with isopropyl alcohol to reduce friction of the silicone to polyurethane, and then quickly sliding the polyurethane insulation tubing over the silicone insulation tubing. After dissipation of the isopropyl alcohol from the interface, such as post implantation, friction should increase significantly such that relative motion between the polyurethane insulation tubing and silicone insulation tubing is prevented.

The Carson reference is cited with respect to the above referenced obviouness rejection because it discloses a lubricious medium comprising a medical grade material. The Carson reference does not disclose or suggest that the flexibility of the membrane and the properties of the lubricious medium enable the flexible membrane to slide over the insulating housing and deform as the lead insulating housing moves relative to a patient's body tissue. Furthermore, the Carson reference does not disclose or suggest that relative motion between the flexible membrane and the insulating housing reduces abrasive wear of the lead body.

Accordingly, it is respectfully submitted that claim 1 is in condition for allowance.

Dependent Claims 2-15 and 22-25

Claims 2-15 and 22-25 depend from claim 1 and are similarly patentable. Furthermore, the Helland et al. reference does not disclose or suggest what is recited in claim 23 of the present application: a fluid-tight chamber having a first surface defined by the outer surface of the insulating chamber and a second surface defined by the inner surface of the membrane.

Accordingly, it is respectfully submitted that these claims are in condition for allowance.

PATENT

CONCLUSION

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

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